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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,403	06/20/2005	Jose Manuel Francisco Lara Ochoa	2099.0090000	3497

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EXAMINER	
RAE, CHARLESWORTH E	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
06/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,403	OCHOA, JOSE MANUEL FRANCISCO LARA	
	Examiner	Art Unit	
	Charleswort Rae	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response with traverse to the restriction requirement electing invention I is acknowledged and made of record.

Upon reconsideration, the restriction requirement, of 12/5/06, is withdrawn.

Status of the Claims

Claims 1-11 are currently pending in this application and are the subject of this Office action.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 are rejected under 35 USC 102(b) as being anticipated by Chandran et al. (US Patent 6,890,957 B2).

Chandran et al. teach liquid compositions of metformin in an amount ranging from **about 20 /ml to about 400 mg/ml**; metformin is administered in a **therapeutic effective amount ranging from about 10 mg/kg/day to about 40 mg/kg/day** (column 4, lines 4-18; column 15, lines 1-60). Chanran et al. teach that the **metformin or salt**

thereof may be in combination with one or more antihyperglycemic agents; the antihyperglycemic agent may be an oral antihyperglycemic agent e.g. a sulfonyl urea, such as glybyride, glimepride, glipizide, gluclazide, or chlorpropamide or other known sulfonyl ureas or other antihyperglycemic agents which act on the ATP-dependent channel of the B cells (column 8, lines 1-8). Chandran et al. teach that the **metformin or salt are preferably employed in a weight ratio to the sulfonyl urea in the range from about 50:1 to about 300:1** (column 8, lines 14-17). Instant claim 2 recites *"metformin ... in an amount between about 100 to 10,000 mg and glimepiride ... between about 0.1 and 20 mg;"* this limitation overlaps with the teaching of Chanran et al. Instant claim 10 recites a ratio of glimepiride/metformin of *about 2/500 or 1/500*, which reasonably overlaps with the limitations taught by Chandran et al. Chandran et al. teach that that metformin or pharmaceutical salts are in association with a **liquid carrier**, which is reasonably construed to meet the limitation of *"excipient"* recited in instant claims 4, 5, 6, and 7. Chanran et al. teach that if *1000mg of metformin* is to be administered, al that is required is to dispense 10 ml of the liquid formulation (column 15, lines 34-56). Chandran et al. teach a **method of treating hyperglycemia** comprising administering to a patient in need of treatment an antihyperglycemic effective amount of the liquid formulation e.g. **Type II diabetes patient** Chandran et al. also teach that the primary goal in the treatment of diabetes is to maintain blood glucose levels as close to normal as possible (column 1, lines 46-53, and column 3, lines 27-34; column 9, lines 5-10); instant claim 8 is directed to a *method of controlling blood glucose levels in a patient with type 2 diabetes.* Chanran et al. teach that an acid may

be added to the formulation to control pH e.g. hydrochloric acid is preferred (column 7, lines 39-44). Someone of skill in the art would construe "metformin base in the liquid containing hydrochloric acid" to reasonably form metformin hydrochloric acid salt. Instant claim 11 recite the term *"metformin hydrochloride."* Claim 8 recites the term *...metformin, in amounts and weight ratio sufficient to provide a synergistic control of blood glucose levels in a patient with type 2 diabetes;"* the synergistic control of blood glucose levels is construed to be coextensive with the coadministration of metformin and glimepiride in the absence of evidence to the contrary.

Thus, claims 1-11 are anticipated by Changran et al. because the limitations of the instant claims overlap with the teachings of Chanran et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov.

Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

7 June 2007
CER

BRIAN-YONG S. KWON
PRIMARY EXAMINER